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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,187	10/13/2005	Dilson Ferreira da Luz	27037	2219
<sup>20529</sup> THE NATH L <i>A</i>	7590 08/05/201 <b>AW GROUP</b>	EXAMINER		
112 South West	t Street	EASTWOOD, DAVID C		
Alexandria, VA 22314			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			08/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Commence	10/553,187	LUZ, DILSON FERREIRA DA				
Office Action Summary	Examiner	Art Unit				
	David Eastwood	3731				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w.  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	l. lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>25 Ju</u>	ne 2010.					
	action is non-final.					
<del></del>	<del>_</del>					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
• 4)⊠ Claim(s) <u>1-17 and 21-23</u> is/are pending in the application.						
4a) Of the above claim(s) <u>1-16</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>17 and 21-23</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers	·					
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>13 October 2005</u> is/are: a) accepted or b)⊠ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)  A) Interview Summary (PTO-413)  Discrete of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08)  Tupor Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) Other:						

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#### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/25/2010 has been entered.

# Response to Amendment

Receipt is acknowledged of applicant's amendment filed 6/25/2010. Claims 18-20 have been canceled without prejudice. Claims 1-16, stand withdrawn and claims 17, 21-23 are pending and an action on the merits is as follows.

Applicant's argument's with respect to the newly presented limitations in amended claim 17 and new claims 21-23 have been fully considered and are addressed by a new ground of rejection as set forth below.

## **Drawings**

2. The drawings are objected to because the drawing contain faded drawings, blurred or illegible text or drawings, skewed slanted images and color or black and white photographs. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the

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immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claims 17 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 17 recites "sectioning the at least one tapered blood vessel by progressively stretching the tapered blood vessel" which is in

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direct conflict and contradiction to the method described in page 7 lines 19-22 and page 8 lines 1-3 of the specification which recites "the vascular extremities, which were subjected to progressive stretching with substantial tapering of their lumens prior to sectioning", it would appear that the "sectioning" is not performed by progressive stretching with substantial tapering since this step is performed prior to the "sectioning" step which is only nominally recited. There is no clear explanation as to what "sectioning" is, what it does or how it is accomplished with the disclosed device. There is only a mere nominal recitation that "the cited device allows the sectioning of the vascular intima". Claim 17 also recites "tapering at least one blood vessel in the marked tissue area", there appears to be no support for this limitation in the specification. The specification only recites this limitation on page 7 lines 19-22 and page 8 lines 1-3 with no reference to where this step is completed but merely recites a tapering step before "sectioning" (note reference to the sectioning limitation discussed above). There is no mention of completing the aforementioned step in the "marked tissue area".

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- 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 6. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 7. Claim 22 recites the limitation "the cutaneous tissue area" in line 2 of claim 22. There is insufficient antecedent basis for this limitation in the claim.

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8. It is not clear whether "the cutaneous tissue area" is the tissue area marked in step a or if it is some other cutaneous tissue area near the operative field.

# Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 11. Claims 17 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over John A. McCurdy M.D. (The Complete Guide to Cosmetic Facial Surgery 1981) in view of Luiz S. Toledo, M.D. (Video-Endoscopic Facelift Aesth. Plast. Surg. 18:149-152, 1994) (hereafter Toledo) further in view of Zucherman et al. (US 2003/0018350) (hereafter Zucherman).

Regarding claim 17, McCurdy discloses a method of cutaneous tissue detachment comprising marking an area for cutaneous tissue detachment (p. 118 third

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paragraph) making the appropriate incisions (p.118 third paragraph) and dissecting the skin from the underlying facial tissue (p. 119 first paragraph). McCurdy fails to explicitly disclose b.) forming at least two cutaneous tissue incisions of approximately 2.5 cm each c.) passing a first rod having a first diameter through the entire marked cutaneous tissue area, d.) passing at least a second rod having a second rod diameter greater than the first rod diameter through the entire marked cutaneous tissue area, e.) tapering at least one blood vessel in the marked tissue area, f.) sectioning the at least one tapered blood vessel by progressively stretching the tapered blood vessel, g.) causing formation of one or more blood clots in a tapered portion of the sectioned vessel and h.) incarcerating the one or more formed blood clots in an extremity of the sectioned vessel until blood no longer flows past the one or more incarcerated clots, wherein steps c-h are performed without cauterization. However, Toledo discloses a method of cutaneous tissue detachment comprising the steps of forming at least two cutaneous tissue incisions of approximately 2.5 cm each and proceeds to dissect the selected tissue (C2 L30-33, end of page where 2 cm is interpreted to be approximately 2.5 cm). It would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Toledo to the method of McCurdy. Doing so would produce a dissected or detached area which required smaller incisions thus advantageously reducing the amount of scarring to the patient and one of ordinary skill in the art would have been capable of applying this known technique, namely the incision dissection technique of Toledo, to a known method, namely the marking and tissue dissection

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method of McCurdy, that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

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McCurdy and Toledo fail to explicitly disclose the dissection step or tissue detachment steps comprising c.) passing a first rod having a first diameter through the entire marked cutaneous tissue area, d.) passing at least a second rod having a second rod diameter greater than the first rod diameter through the entire marked cutaneous tissue area, e.) tapering at least one blood vessel in the marked tissue area, f.) sectioning the at least one tapered blood vessel by progressively stretching the tapered blood vessel, g.) causing formation of one or more blood clots in a tapered portion of the sectioned vessel and h.) incarcerating the one or more formed blood clots in an extremity of the sectioned vessel until blood no longer flows past the one or more incarcerated clots, wherein steps c-h are performed without cauterization. However, attention is drawn to the disclosure of Zucherman which discloses passing a first rod having a first diameter through the entire marked cutaneous tissue area (para 13 and 15) passing at least a second rod having a second rod diameter greater than the first rod diameter through the entire marked cutaneous tissue area (para. 13 and 15) tapering at least one blood vessel in the marked tissue area (inherently as the tissue around the incision or opening as taught by Zucherman is dilated blood vessels surrounding the aforementioned opening will be subjected to a compressive and stretching force which compresses the vessel stretching it's annular walls deforming it into a tapered shape while stretching the surrounding tissue during dilation), sectioning the at least one tapered blood vessel by progressively stretching the tapered blood

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vessel (a larger diameter rod is introduced by the user, as discussed by Zucherman in order to further dilate the opening, stretching the tissue and associated vessels which are surrounding the tissue opening, thereby sectioning the compressed and stretched portions of the vessels from the rest of the vessel, where sectioning is interpreted to mean tapering the vessel such that larger diameter vessel sections are formed on either side of the tapered section of the vessel thus sectioning the vessel into two larger diameter sections), causing formation of one or more blood clots in a tapered portion of the sectioned vessel (inherently as a vessel under goes substantial stretching, compression and deformation the endothelial cells are disrupted initiating a clot forming sequence) and incarcerating the one or more formed blood clots in an extremity of the sectioned vessel until blood no longer flows past the one or more incarcerated clots (a mentioned above as a larger diameter rod is introduced by the user as discussed by Zucherman this would further dilate the opening stretching the tissue and associated vessels which are surrounding the tissue opening thereby sectioning the compressed and stretched portions of the vessels from the rest to the vessel and incarcerating any clot formation to the tapered portion), wherein the steps are performed without cauterization (para. 13 and 15 where the dilation and dissection steps are recited by Zucherman without cauterizing the tissue). It would have been obvious to one of ordinary skill in the art at the time of invention to apply the dissection and dilation steps as taught by Zucherman to the cutaneous tissue detachment and dissection method as taught by McCurdy and Toledo. Doing so would provide a means for incrementally dissecting the tissue via dilation of the opening or incision thus advantageously

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compressing the surrounding vasculature reducing the amount of blood flow to the operative field and one of ordinary skill in the art would have been capable of applying this known technique, namely the dissection/dilation technique of Zucherman, to a known method, namely the tissue dissection method of McCurdy and Toledo, that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

Regarding claim 21, McCurdy Toledo and Zucherman disclose steps c) through h) are performed without using scissors or a scalpel (note paragraph 13 and 15 of Zucherman and the rejection of claim 17 above where the aforementioned steps c-h are performed with varying diameter rods not with scissors or a scalpel).

Regarding claim 22, McCurdy, Toledo and Zucherman disclosed the claimed invention except for explicitly disclosing steps c-h are repeated until approximately 90% of the cutaneous tissue area is detached from the underlying fatty tissue. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to repeat steps c-h until approximately 90% of the cutaneous tissue area is detached from the underlying fatty tissue, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 23, McCurdy, Toledo and Zucherman disclose the first and second rod diameters are between 1.5 mm and 20 mm (paragraph 12 of Zucherman).

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#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Eastwood whose telephone number is (571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. E./ Examiner, Art Unit 3731 7/22/2010

/Gary Jackson/ Supervisory Patent Examiner Art Unit 3731/34/73 August 1, 2010